Supreme Court, U.S.
FILED

10-1031 FEB 16 2011

OFFICE OF THE CLERK

No.

In the Supreme Court of the United States

NATIONAL CORN GROWERS ASSOCIATION, ET AL.,
Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY, ET AL.,
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

For nearly forty years, the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 346a(g)(2)(B), has required the Environmental Protection Agency (EPA) to hold a public evidentiary hearing before taking certain major agency actions, when a party objects to the proposed action and satisfies what the agency itself has described as "summary judgment-type procedures" that, among other things, require a hearing to resolve "disputed material factual issues." 74 Fed. Reg. 59,608, 59,623 (Nov. 18, 2009); *see* 40 C.F.R. § 178.32(b). During that time, EPA has never held such a hearing.

In this case, EPA refused to hold such a hearing before revoking the tolerances for—and thus effectively banning—a pesticide that has been used safely for decades, even though petitioners filed timely objections supported by ample expert data and other evidence calling into serious question the agency's findings on several material issues of fact. The District of Columbia Circuit upheld EPA's decision, holding that review of such a denial is highly deferential, that—paradoxically—the existence of an expert dispute over a critical factual issue was "fatal" to petitioners' request for a hearing, and that the agency properly refused to consider various objections based on "Catch-22" timing considerations. App.7a-13a.

If a hearing is not required under the FFDCA in this type of case, then as a practical matter the Act's hearing requirement is illusory. The question presented is whether the District of Columbia Circuit—in conflict with the decisions of this Court and other circuits, as well as with the agency's own regulations—has properly construed the FFDCA's hearing requirement and related rules.

LIST OF PARTIES AND RULE 29.6 STATEMENT

Petitioners are the National Corn Growers Association, National Sunflower Association, National Potato Council, and FMC Corporation.

The National Corn Growers Association is a non-publicly held, not-for-profit 501(c)(5) corporation organized and existing under the laws of the State of Iowa. The National Corn Growers Association does not have a parent corporation. There is no publicly held corporation owning 10% or more of the National Corn Growers Association.

The National Sunflower Association is a non-profit commodity organization existing under the laws of the State of North Dakota. The National Sunflower Association does not have a parent corporation. There is no publicly held corporation owning 10% or more of the National Sunflower Association.

The National Potato Council is a non-publicly held 501(c)(5) not-for-profit corporation organized and existing under the laws of the State of Colorado. The National Potato Council does not have a parent corporation. There is no publicly held corporation owning 10% or more of the National Potato Council.

FMC Corporation is a publicly-traded corporation that has no parent organization. No publicly-held entity owns more than 10% of FMC Corporation.

Respondents are the U.S. Environmental Protection Agency (EPA) and Lisa P. Jackson, the Administrator of EPA.

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TABLE OF AUTHORITIES

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Juliet Eilperin, *In Surprise Move, EPA Bans Carbofuran Residue on Food*, Washington Post, July 25, 2008 10

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PETITION FOR A WRIT OF CERTIORARI

Petitioners, the National Corn Growers Association, *et al.*, respectfully petition for a writ of certiorari to review the judgment of the District of Columbia Circuit in this case.

OPINIONS AND ORDERS BELOW

The District of Columbia Circuit's opinion (App.1a-15a) is reported at 613 F.3d 266. EPA's final order denying petitioners' objections and hearing requests is reported at 74 Fed. Reg. 59,608, and reproduced at App.16a-342a. EPA's final revocation order is reported at 74 Fed. Reg. 23,046, and excerpts of that order are reproduced at App.343a-68a. EPA's proposed revocation order is reported at 73 Fed. Reg. 44,864, and excerpts of that order are reproduced at App.369a-76a.

JURISDICTION

The District of Columbia Circuit entered judgment on July 23, 2010, and denied timely petitions for rehearing and rehearing en banc on October 19, 2010. On December 23, 2010, the Chief Justice extended the time within which to file a petition for a writ of certiorari to and including February 16, 2011. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL, STATUTORY, AND REGULATORY PROVISIONS INVOLVED

The Due Process Clause of the Fifth Amendment to the Constitution provides in relevant part: "No person shall ... be deprived of life, liberty, or property, without due process of law ...." U.S. Const. amend. V, cl. 3.

Section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 346a(g), states in relevant part:

> Within 60 days after a regulation or order is issued under subsection (d)(4), (e)(1)(A), (e)(1)(B), (f)(2), (n)(3), or (n)(5)(C), any person may file objections thereto with the Administrator, specifying with particularity the provisions of the regulation or order deemed objectionable and stating reasonable grounds therefor. ... An objection may include a request for a public evidentiary hearing upon the objection. The Administrator shall, upon the initiative of the Administrator or upon the request of an interested person and after due notice, hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections.

Other relevant portions of the FFDCA and regulations of the U.S. Environmental Protection Agency (EPA) are set forth at App.382a-433a.

INTRODUCTION

The ability to obtain a live hearing before a neutral factfinder to resolve material issues of disputed fact is a time-honored feature of our system of justice. As this

Court has observed, "[c]ertain principles," such as "confrontation and cross-examination," "have ancient roots" and "have remained relatively immutable in our jurisprudence." *Greene v. McElroy*, 360 U.S. 474, 496-97 & n.25 (1959). Indeed, a live hearing with cross-examination is the "greatest legal engine ever invented for the discovery of truth." *California v. Green*, 399 U.S. 149, 158 (1970) (quotation marks and citation omitted). For that reason, "'[t]his Court has been zealous to protect these rights from erosion. It has spoken out not only in criminal cases, but also in all types of cases where administrative actions were under scrutiny.'" *Goldberg v. Kelly*, 397 U.S. 254, 270 (1970) (quoting *Greene*, 360 U.S. at 497) (alterations omitted).

At issue here is Congress's requirement under the FFDCA that EPA must conduct a live hearing on revocation of pesticide "tolerances" (*i.e.*, limits of residues) when there are material issues of fact as to the safety of the pesticide and other factors. *See* 21 U.S.C. § 346a(g). By EPA's admission, the FFDCA imposes a "'summary-judgment type' standard" in deciding when a hearing is required. App.6a. But in the four decades that EPA has administered this hearing requirement—a provision that tracks similar hearing requirements for other agency actions—EPA has never conducted such a hearing. And in this case, the agency refused to conduct a hearing before banning a pesticide—carbofuran—that has been used safely for decades, notwithstanding the existence of several disputed issues of material fact and a prototypical battle of the experts going to the heart of the agency's determination that the product was unsafe.

In the decision below, the District of Columbia Circuit upheld EPA's refusal to hold a hearing,

adopting a standard for determining when a hearing is due under the FFDCA that effectively eviscerates the Act's hearing requirement. For example, even though the court recognized that the FFDCA and EPA's own regulations adopt "a 'summary-judgment type' standard" under which a hearing is required to resolve "material issue[s] of fact," App.6a, the court concluded that "a 'dispute between experts'" on a critical factual issue was "fatal" to petitioners' hearing request. App.13a. In addition, the court embraced a novel and far-reaching timing rule that gives EPA virtually free rein to reject evidence and arguments in support of hearing requests as either "too early" or "too late" under arbitrary, "Catch-22" timing considerations.

The District of Columbia Circuit's decision effectively eviscerates a critical statutory right and curtails the public's ability to challenge an agency's manipulation of disputed facts to reach a desired policy end. The decision conflicts not only with the agency's own regulations, but with decisions of this Court and other circuits. And the decision has far-reaching significance because the hearing requirement at issue is comparable to other hearing requirements governing administrative actions by EPA, the Food and Drug Administration (FDA), and the Consumer Products Safety Commission (CPSC) affecting a major segment of the nation's economy—including prescription drugs, medical devices, agriculture, food products and additives, and many other consumer products. As the most important circuit in the country for administrative law, the District of Columbia Circuit's ruling on the standard for obtaining a hearing under common administrative summary-judgment procedures is a matter of exceptional importance.

Certiorari is warranted to resolve the multifaceted conflicts of authority created by the decision below and to restore a critical statutory safeguard that Congress has granted the public on matters of enormous economic and public policy significance.

STATEMENT OF THE CASE

A. Background

1. *Statutory and Regulatory Background*

Pesticides are regulated under both the FFDCA and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136 *et seq.* *See CropLife Am. v. EPA*, 329 F.3d 876, 879 (D.C. Cir. 2003). "FIFRA establishes a registration system allowing EPA to prescribe the conditions under which a pesticide may be sold or distributed." *Id.* Under FIFRA, EPA considers whether a pesticide "would cause 'unreasonable adverse effects on the environment,'" which includes "'unreasonable risk to man' or any 'human dietary risk.'" *Id.* (citation omitted). EPA also establishes "tolerance levels"—*i.e.*, "the amount of pesticide that may remain on food products"—under the FFDCA. *Id.* The FFDCA, in turn, "defines pesticide tolerances as 'safe' when there is 'a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue.'" *Id.* (quoting 21 U.S.C. § 346a(b)(2)(A)(ii)).

Under this scheme, the ability to sell a pesticide depends on the existence of a tolerance. EPA's ability to grant or revoke tolerances is circumscribed by a bifurcated rulemaking process: an initial informal rulemaking on a proposed and final order of revocation; and if contested, a second formal rulemaking that permits a party to object to the final order and request

an on-the-record hearing. 21 U.S.C. § 346a(g); *see* Richard A. Merrill & Michael Schewel, *FDA Regulation of Environmental Contaminants of Food*, 66 Va. L. Rev. 1357, 1382 (1980). The FFDCA provides that after EPA issues a "final regulation ... establishing, modifying, or revoking a tolerance," "any person may file objections thereto with the Administrator" and request "a public evidentiary hearing upon the objection." 21 U.S.C. § 346a(d)(4)(A)(i), (g)(2)(A), (g)(2)(B). The Act further states that EPA "shall, ... hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections." *Id.* § 346a(g)(2)(B).

EPA's regulations governing such hearings (40 C.F.R. § 178.32(b)) create "summary judgment-type procedures" wherein a hearing will be granted upon request if petitioners raise material issues of fact. 73 Fed. Reg. 42,683, 42,694 (July 23, 2008); App.6a. EPA's "hearing request requirements are based heavily on FDA [hearing] regulations." App.82a; *see* 21 C.F.R. §§ 12.24, 314.126, 314.200. FDA's regulations, in turn, are "modeled after Rule 56 of the Federal Rules of Civil Procedure," *USV Pharm. Corp. v. Secretary of Health, Education & Welfare*, 466 F.2d 455, 461 (D.C. Cir. 1972), and reflect the guidance in this Court's decision in *Weinberger v. Hynson, Wescott & Dunning, Inc.*, 412 U.S. 609 (1973), which laid out several basic principles governing administrative summary judgment under the FFDCA. *See* 40 Fed. Reg. 22,950, 22,968 (May 27, 1975) (explaining that FDA's summary-judgment procedures "accurately reflect the legal standards enunciated by" *Weinberger*).

2. *Carbofuran And Its Uses*

This case involves the pesticide carbofuran, which since 1969 has been registered by EPA as meeting the human health and environmental safety requirements of FIFRA and the FFDCA. JA-162.[1] Carbofuran is a "cholinesterase inhibitor," which acts by inhibiting nervous system communication. JA-147, 166-67. When carbofuran is present below threshold levels, however, no adverse effects occur. *See* App.345a, 27a. In addition, the effects of carbofuran are rapidly reversible. JA-168. Recovery from carbofuran exposures begins within 15 to 40 minutes of exposure, with a half-life of approximately 2.5 hours and full recovery occurring within 24 hours. JA-621, JA-168. Because of the rapid recovery time, chronic exposures to carbofuran do not present a health risk. JA-168.

Carbofuran has been used safely for decades to control pest infestations in a variety of crops, including corn, sunflowers, pumpkins, and potatoes. *See generally* App.54a, 345a; JA-199-214. At its peak in the late 1980s, carbofuran was approved for use on 35 domestic crops and approximately 10-11 million pounds were applied annually. 50 Fed. Reg. 41,938, 41,941 (Oct. 16, 1985); App.344a-45a. With the emergence of new pesticides and other factors, carbofuran subsequently transitioned to a niche product for specific pest control problems. JA-361, 194-95. Current carbofuran usage (before EPA's ban took effect in December 2009) is about 200,000 pounds per year—a 98% reduction from peak levels. *See, e.g.*, App.501a-02a. There has never been a documented

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[1] "JA" refers to the joint appendix filed in this case in the United States Court of Appeals for the District of Columbia Circuit.

incident of any person suffering adverse health effects from dietary exposures to carbofuran, either from food or drinking water. JA-339-44.

The remaining domestic carbofuran uses have few, if any, effective alternatives, and the economic impact of banning carbofuran is therefore significant. Banning carbofuran is estimated to cost growers, applicators, vendors, and the downstream farm economies $86-254 million from the loss of carbofuran on corn, $56-190 million from its loss on potatoes, and $13-22 million from its loss on sunflowers. JA-201, 208-09, 214.[2]

B. Proceedings Below

1. *Proposed Revocation And Comments*

On July 31, 2008, EPA proposed to revoke carbofuran's tolerances under the FFDCA—an action that would effectively ban any domestic carbofuran use. *See generally* 73 Fed. Reg. 44,864 (July 31, 2008). EPA has admitted that there is *no* danger from carbofuran residues on food. *See, e.g.*, App.343a-45a; App.14a. As a result, EPA's proposed tolerance revocation rested on one narrow basis: potential exposures from drinking water drawn from ground or surface water sources. App.345a-47a.

In response to EPA's proposed tolerance revocation order, petitioners submitted extensive comments and supporting extensive evidence—including expert analyses—demonstrating that exposures from surface and drinking water were safe, and contesting EPA's estimates of exposure levels and the safe dosage of

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[2] Carbofuran also has tolerances approved by EPA for imported crops of sugarcane, coffee, bananas, and rice. EPA has admitted that residue levels on these crops are safe. App.14a.

carbofuran (which all parties agree is non-zero). *See generally* JA-601-775. At the same time, to address any potential concerns about possible water exposures, petitioners voluntarily cancelled most carbofuran uses, App.457a-59a, restricted the geographic areas where carbofuran could be used, App.465a-66a, 476a-77a, and reduced the maximum application rates for particular crops. App.477a-78a. Petitioners also provided data showing that carbofuran usage would not exceed 4.25% in *any* watershed, and that, based on EPA's own modeling, such usage levels were safe. App.448a-49a.

2. ***Final Revocation Order***

EPA published a final revocation order on May 15, 2009, with an effective date of December 31, 2009. 74 Fed. Reg. 23,046, 23,088 (May 15, 2009). Ignoring petitioners' data showing that carbofuran usage did not exceed 4.25% in any watershed, EPA assumed that *100%* of crops that could be treated with carbofuran would be so treated, simply because it "remains legally permissible for 100% of [a given watershed] to be treated with carbofuran." App.350a. Based on that unrealistic assumption, EPA concluded that carbofuran usage did not meet the FFDCA safety standard. App.235a-36a, 4a-8a. In response to petitioners' comments, EPA also adjusted its groundwater modeling using a new, so-called "Wisconsin scenario" that changed the agency's analysis for determining when usage levels were safe. App.362a-65a.

3. ***Objections And Request For A Hearing***

Petitioners filed extensive objections and supporting exhibits challenging EPA's revocation order—and requested a hearing on their objections. *See* App.440a-503a. Petitioners challenged many of the core factual assumptions underlying EPA's revocation

order, proffered extensive evidence and testimony from experts in support of each challenge, and requested a hearing on several outcome-determinative factual issues centered around whether exposures to carbofuran are safe. JA-1145-89. In response to EPA's new "Wisconsin scenario" and assumption of 100% usage, petitioners also submitted a proposal (presented as label amendments under FIFRA) to impose a legally-binding limit on carbofuran usage to no more than 2% of acreage in a watershed, and mandatory setbacks from drinking water wells. *See, e.g.*, App.470a-76a. While petitioners' objections were pending, EPA admitted that there was no imminent danger from current carbofuran use—stating, for example, that "'there is little exposure today,'" and acknowledging that under EPA's own assumptions carbofuran "would rarely pose a risk." Juliet Eilperin, *In Surprise Move, EPA Bans Carbofuran Residue on Food*, Washington Post, July 25, 2008.

5. ***EPA Denial Of Objections And Hearing Request***

Four-and-a-half months after petitioners filed their objections, EPA denied petitioners' objections and hearing requests. *See* App.16a-342a. Although EPA acknowledged that EPA's regulations (40 C.F.R. § 178.32(b)) established a "summary judgment-type" standard for determining when a hearing is required modeled on the hearing requirements at issue in *Weinberger*, App.82a-83a, EPA denied a hearing on bases wholly incompatible with *Weinberger* and any "summary judgment-type" procedure—freely drawing inferences in its own favor, weighing the evidence itself, dismissing opposing experts' opinions without

challenging their qualifications, and rejecting evidence simply because *it* was not convinced to change course.[3]

EPA also categorically disregarded important aspects of petitioners' objections and submission. Although both the FFDCA (21 U.S.C. § 346a(g)(2)(A)) and the agency's own rules (40 C.F.R. § 178.20(a)) explicitly allow parties to raise objections *after* a final revocation order is issued, EPA declared that contentions raised in comments on EPA's *proposed* revocation were conclusively addressed in the final revocation order and thus refused to consider certain objections on the ground that they purportedly were "recycled." App.23a. At the same time, EPA deemed "too late" any data, issue, argument, or factual detail not specifically raised in petitioners' comments on the proposed revocation, even though EPA had a full opportunity to address these points in its extensive denial of objections and hearing request. *See* App.311a.

Tellingly, EPA even refused to consider objections to new positions adopted by EPA in its final revocation order that petitioners could not challenged earlier. For example, even though EPA first unveiled its new "Wisconsin scenario" in its final revocation order, EPA

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[3] EPA's order is replete with such analysis. *See, e.g.*, App.127a (weighing the "totality of the evidence" to deny petitioners' hearing request); *id.* (concluding "sum of [petitioners'] evidence ... falls far short"), App.152a (arguing "Petitioners' evidence does not demonstrate that reliance on juvenile brain data ... will guarantee that the levels chosen ... will be predictive [of effects]"), App.182a (rejecting "Petitioners' suggested approach" because, in its judgment, it was "scientifically invalid"), App.207a (contending "evidentiary proffer does not support their contention"); App.209a (arguing evidence "provided is insufficient to allow EPA to confirm the Petitioners' contention"); App.218a (concluding "evidentiary proffer in support of this objection is inadequate").

refused to consider petitioners' proposed use of setbacks from drinking wells to address this new modeling scenario on the ground that the objection was "too late" because it was not raised in petitioners' comments. But petitioners' comments could not have addressed a modeling scenario introduced for the first time in EPA's revocation order. *See* App.60-63a.

6. ***District Of Columbia Circuit Decision***

Petitioners sought review of EPA's revocation order and challenged, *inter alia*, EPA's denial of a hearing. The District of Columbia Circuit affirmed EPA's hearing denial order in broad terms. App.1a-15a. The court recognized that "the FFDCA and the EPA's regulations establish a 'summary-judgment type' standard for determining whether to hold a hearing: The EPA must hold a hearing if it determines an objection raises a material issue of fact." App.6a. However, the court declined seriously to entertain whether the agency actually applied a "'summary-judgment type' standard," and adopted a "necessarily deferential" standard for reviewing the agency's denial of a hearing request. App.6a-7a. The court also upheld EPA's refusal to consider objections based on EPA's newfound, Catch-22 timing rules. App.8a-13a.

The District of Columbia Circuit's standard of review looked only to "'whether [the agency] has given adequate consideration to all relevant evidence,'" and thus effectively gave the agency *carte blanche* to decide "'factual matters'" within the agency's area of expertise. App.7a (alteration in original) (citations omitted). Applying that standard, the court affirmed EPA's 100% usage assumption for surface water, even though petitioners' expert data showed that actual usage did not exceed 4.25% in any relevant area. And

the court held that an admitted "dispute between experts" was "*fatal*" to petitioners' request for a hearing. App.13a (emphasis added). In the court's view, neither a dispute among accredited experts nor "'differences in the weight or credence given to particular scientific studies'" were sufficient to create a material dispute of fact. *Id.* (citation omitted).[4]

7. ***EPA's Subsequent Hearing Denial***

EPA wasted little time in pressing the District of Columbia Circuit's decision in this case into service of its four-decade-long refusal to hold hearings, using it to support EPA's denial of a hearing request by the Natural Resources Defense Council (NRDC) on its petition seeking the revocation of tolerances for the pesticide carbaryl. 75 Fed. Reg. 55,997 (Sept. 15, 2010). EPA's order cites the District of Columbia Circuit's decision in this case in both narrowing the objections that the agency considered and in arrogating to the agency the authority to weigh the evidence itself, make credibility determinations, and simply disregard contrary expert evidence. *Id.* at 56,007, 56,010-12.

REASONS FOR GRANTING THE WRIT

The District of Columbia Circuit's decision in this case upholding EPA's refusal to grant an evidentiary hearing under the FFDCA before banning a product used safely for decades warrants this Court's review for three principal reasons. First, the court's conception of when a hearing is required under the

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[4] In light of EPA's own admission that the import tolerances for carbofuran were "safe," the panel set aside EPA's revocation of those tolerances as "requir[ing] no display of learning." App.14a. That ruling is not challenged here.

FFDCA conflicts not only with the agency's own rules establishing that a "'summary-judgment type' standard" (App.6a) governs, but with this Court's decision in *Weinberger v. Hynson, Wescott & Dunning, Inc.*, 412 U.S. 609 (1973), and with the decisions of other circuits. Second, the court's endorsement of EPA's novel rule allowing the agency categorically to reject objections as either "too early" or "too late" compounds the damage done by the court's ruling on when a hearing is due, directly contravenes the FFDCA and EPA's own rules, and conflicts with the decisions of this Court and other circuits on when an agency may invoke waiver. And third, the court's decision eviscerates a critical statutory right designed to protect the public in a wide array of matters of great economic and public policy significance.

I. THE DISTRICT OF COLUMBIA CIRCUIT'S DECISION ON THE STANDARD FOR WHEN A HEARING IS REQUIRED UNDER THE FFDCA MERITS THIS COURT'S REVIEW

Nearly four decades ago, in *Weinberger*, this Court approved the use of administrative summary-judgment procedures under the FFDCA. But in doing so, the Court articulated important limits on that power to ensure that those procedures remained faithful to the bedrock principles of summary judgment and that agencies—which invariably regard evidentiary hearings before neutral factfinders as an unwelcome intrusion on their decision-making—did not abuse those procedures and thereby render parties' right to a hearing a nullity. *See* 412 U.S. at 620-23. The decision below vitiates those important safeguards, conflicts

with *Weinberger* and decisions of other courts, and effectively eviscerates this important hearing right.

A. The Decision Below Is Fundamentally Incompatible With Any "'Summary-Judgment Type' Standard" And Nullifies The FFDCA's Hearing Right

1. As the court of appeals observed, "[t]he parties agree that the FFDCA and the EPA's regulations establish a 'summary-judgment type' standard for determining whether to hold a hearing: The EPA must hold a hearing if it determines an objection raises a material issue of fact." App.6a; *see* App.82a (recognizing that EPA's regulations adopt "summary judgment-type procedures" under which a hearing is available for "disputed material factual issues"). The court of appeals' decision, however, is fundamentally incompatible with any "'summary-judgment type' standard." Indeed, the court's decision eliminates what the court itself recognized is the hallmark of any summary judgment-type procedure: the entitlement to a hearing to resolve disputed issues of material fact. The decision below likewise contravenes a central purpose of FFDCA § 408(g): to require that disputes over material issues be tested by the adversarial process, rather than allowing EPA to cherry pick opinions supporting its preferred outcome.

2. As the agency has frankly observed, EPA views hearings under the FFDCA as "time-consuming" and "unnecessary," EPA D.C. Cir. Br. 5, 56 (filed Feb. 3, 2010)—in short, an unwelcome addition to, and intrusion into, the agency's own decision-making. As a result, although EPA's regulations indisputably adopt summary judgment-type procedures requiring a hearing to resolve disputed issues of material fact,

EPA has utterly disregarded those procedures and, tellingly, has *never* found a single issue of material fact on which it believed a hearing was required in the four decades it has administered the FFDCA.[5]

EPA's denial of a hearing on the record in this case flouts several essential features of any meaningful "summary judgment-type standard." *First*, a bona fide dispute among experts over material facts is a paradigmatic situation where a hearing is required. *See, e.g.*, *Phillips v. Cohen*, 400 F.3d 388, 399 (6th Cir. 2005); *Trunk v. City of San Diego*, Nos. 08-56415, 08-56436, 2011 U.S. App. LEXIS 53, at *35 n.12 (9th Cir. Jan. 4, 2011). Here, the court of appeals recognized that both sides had presented expert testimony on outcome determinative, and thus material issues, such as the concentration of carbofuran in groundwater. App.11a-13a. Yet, the District of Columbia Circuit—turning this bedrock summary judgment principle on its head—held that a "'dispute between experts'" was "fatal" to obtaining a hearing. App.13a.

Second, another classic feature of any "summary judgment-type" procedure is that "all justifiable inferences are to be drawn" against the party opposing a trial/hearing (here, EPA). *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). But the court of appeals permitted EPA to deny a hearing by drawing the patently absurd inference that crop treatment

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[5] *See, e.g.*, 75 Fed. Reg. 55,997 (denying hearing); 73 Fed. Reg. at 42,710 (same) ("EPA has not held any pesticide tolerance hearings under the FFDCA."); 53 Fed. Reg. 41,126, 41,127 (Oct. 19, 1988) (same); 72 Fed. Reg. 39,318, 39,323-24 (July 18, 2007) (denying hearing request); 59 Fed. Reg. 33,684 (June 30, 1994) (same).

levels would be *100%* in a watershed, even though petitioners' experts showed that actual usage did not exceed 4.25% in any relevant area—a factual issue that is outcome-determinative as to the safety of exposures from surface water. App.7a, 10a-11a, 449a-54a. Indeed, even EPA admitted that its assumption of 100% usage was "unlikely ... [to occur] in most watersheds." App.235a-36a; *accord* App.349a. To say the least.

Third, it is well-settled that, in determining whether to hold a hearing, a "judge's function is not himself to weigh the evidence." *Anderson*, 477 U.S. at 249. But in denying a hearing, EPA repeatedly did just that, acting as both a litigant *and* judge and denying a hearing on the ground that *it* was not persuaded to alter its own decision. *See, e.g.*, App.127a-28a, 152a, 182a, 207a, 209a-10a, 291a. The District of Columbia Circuit acquiesced—holding that "'[m]ere differences in the weight'" of the evidence could not justify a hearing. App.7a (citation omitted). Yet differences in the weight of evidence that can justify different outcomes are often precisely why our system requires hearings and trials. *Anderson*, 477 U.S. at 255 ("[T]he weighing of the evidence ... [is a] jury function[], not [one] of a judge ...."). And if Congress had wanted to give EPA free rein to make such determinations it would not have required hearings before *neutral* arbiters to resolve disputed issues of material fact.

3. Instead of enforcing the "'summary judgment-type' standard" that the court of appeals itself recognized was established by EPA's own rules, the court held that its review of EPA's hearing denial was "necessarily deferential" and then broadly deferred to EPA's decision that a hearing was not required. App.6a-7a. There are several fundamental problems

with that approach. First, as explained in the next section, the District of Columbia Circuit's highly deferential standard of review directly conflicts with this Court's decision in *Weinberger*. Second, no measure of deference—not even arbitrary-and-capricious review—may excuse the denial of a hearing under a legally erroneous standard. *See, e.g.*, *Mountain Side Mobile Estates P'ship v. Secretary of HUD*, 56 F.3d 1243, 1250 (10th Cir. 1995); *cf.* 5 U.S.C. § 706(2). And third, an agency decision must be set aside if it does not meet statutory or regulatory requirements. *See Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 413-14 (1971). Here, EPA's denial of a hearing was based on a standard that flouts the "'summary judgment-type' procedures" undeniably required by the agency's own rules. App.82a-83a.

4. The upshot is that the court of appeals' decision essentially eviscerates the hearing right under the FFDCA and the agency's own rules. As the Fourth Circuit observed in refusing to permit an agency to engage in the same sort of tactics to deny a hearing under the very procedures on which EPA's summary judgment-type standard was modeled, if the "predicate for securing [the] right to a hearing" is that the proponent's evidence must be sufficient to convince the agency to change its decision—not just sufficient to create a material issue of disputed fact—then "a hearing would be useless and the Congressional promise of a hearing would be purely illusory." *Hynson, Westcott & Dunning, Inc. v. Richardson*, 461 F.2d 215, 220 (4th Cir. 1972) ("*Hynson*"). EPA's hearing denial on the record here likewise renders the FFDCA's hearing requirement "purely illusory."

Commentators have long recognized that agencies have institutional incentives (like retaining control over their own decision-making process) to manipulate administrative summary-judgment procedures as a "hearing-avoidance technique." Charles C. Ames & Steven C. McCracken, *Framing Regulatory Standards to Avoid Formal Adjudication: The FDA As a Case Study*, 64 Cal. L. Rev. 14, 30 (1976) (heading); *see id.* (noting that FDA has succeeded in eliminating hearings over "all but the most unusual factual contentions"). EPA—which dismissively refers to hearings as "time-consuming" and "unnecessary," EPA D.C. Cir. Br. 5, 56, and in nearly 40 years has never held a hearing under the provision at issue—has taken this "hearing-avoidance technique" to the extreme.

The nullification of an Act of Congress ordinarily is a compelling reason for granting certiorari. *See, e.g.*, *United States v. Powell*, 423 U.S. 87, 88 (1975). It is a particularly strong reason here. The right to a hearing before a neutral and detached factfinder to resolve disputed issues of material fact is a vital and time-honored safeguard. As this case well illustrates, EPA—like other agencies—is not programmed to second-guess its own conclusions and institutional biases. *Cf. Ramaprakash v. FAA*, 346 F.3d 1121, 1122 (D.C. Cir. 2003) ("Learned Hand once remarked that agencies tend to 'fall into grooves, and when they get into grooves, then God save you to get them out.'") (Roberts, J.) (alteration and citation omitted). It is therefore critical that courts ensure that EPA at least abide by its own "summary-judgment type standard" in determining when a hearing before a neutral finder of fact is required to resolve material factual issues.

B. The Decision Below Conflicts With This Court's Decision In *Weinberger* As Well As Decisions Of Other Circuits

1. The District of Columbia Circuit's decision flies in the face of this Court's seminal decision on administrative summary-judgment procedures in *Weinberger*. In *Weinberger*, this Court affirmed the Fourth Circuit's decision *reversing* FDA's denial of a hearing under the FFDCA in considering whether to withdraw approval of a new drug application. 412 U.S. at 616-23. As EPA explained in the challenged order, the "summary judgment-type procedures" governing the hearing requirement at issue in this case are "based heavily" on the procedures that this Court embraced in *Weinberger*. App.82a. The Court's decision in *Weinberger* therefore supplies a clear baseline for determining when a hearing is required under the "'summary-judgment type' standard" that indisputably (App.6a) governs the hearing requirement this case.

The decision below conflicts with *Weinberger* in three fundamental respects. *First*, in *Weinberger*, this Court recognized that administrative summary judgment is appropriate only "where it is apparent at the threshold that the applicant has not tendered *any* evidence which *on its face* meets the statutory standards as particularized by the regulations." 412 U.S. at 620 (emphasis added). This standard parallels the standard for granting summary judgment, under which a trial can be denied only if the record reveals "there can be but one reasonable conclusion as to the verdict." *Anderson*, 477 U.S. at 250. In this case, by contrast, the District of Columbia Circuit properly characterized the essence of the disagreement between petitioners and EPA as a "dispute between experts"

about dispositive facts. App.13a. But, as discussed, the court paradoxically reasoned that such a dispute was "fatal" to petitioners' hearing request. *Id.*

Second, in *Weinberger*, this Court made clear that a reviewing court should engage in a meaningful—and thus not unduly deferential—inquiry into whether a hearing was required. The Court admonished that, "[i]n reviewing an order of the Commissioner denying a hearing, a court of appeals must determine whether the Commissioner's findings accurately reflect the study in question and if they do, whether the deficiencies he finds conclusively render the study inadequate or uncontrolled in light of the pertinent regulations." 412 U.S. at 622. This standard of review ensures that an agency may properly deny a request for a hearing only "when it appears *conclusively* from the applicant's '*pleadings*' that the application cannot succeed," *id.* at 621 (emphases added), and thus squares with a customary summary judgment-type standard.

In contrast, the District of Columbia Circuit applied a "necessarily deferential" standard of review "'limited to an evaluation of whether [the agency] has given adequate consideration to all relevant evidence in the record.'" App.7a (citation omitted). And the answer even to this hands-off inquiry was all but preordained because the court refused to evaluate the agency's characterization of petitioners' expert evidence, stating instead that it "'will not substitute [its] judgment on highly technical and factual matters for that of the agency.'" *Id.* (citation omitted). But as *Weinberger* underscores, whatever deference an agency typically is owed on "highly technical" or scientific matters, agencies do not enjoy *carte blanche* in deciding whether there are material issues of disputed facts

over technical or scientific issues.

Third, in *Weinberger*, the Court admonished that the general rule that administrative summary judgment is warranted "when it appears conclusively from the applicant's 'pleadings' that the application cannot [satisfy the regulatory requirements for a hearing]," 412 U.S. at 621, "applies, of course, *only to those regulations that are precise*," such as a rule requiring a study to include "[a] summary of the methods of analysis," *id.* at n.17 (emphasis added). In contrast, the Court explained, more subjective, "qualitative standards"—like those directing applicants to produce "adequate" or "suitable" data—"do not lend themselves to clear-cut definition," and thus do not lend themselves to summary disposition. *Id.*

In this case, EPA has failed to provide any clear, objective standards that might support a conclusion that petitioners' proffer was "conclusively" inadequate on its face. Instead, EPA rejected petitioners' scientific evidence because it concluded there was not a "*reasonable possibility*" that petitioners' evidence was "[]*sufficient* to justify the factual determination urged." 40 C.F.R. § 178.32(b)(2) (emphasis added); *see, e.g.*, App.78a, 267-68a, 334a. But these are just the sort of inherently "qualitative"—and thus more subjective—standards that the *Weinberger* Court held were less amendable to administrative summary judgment. *See Weinberger*, 412 U.S. at 621 n.17.[6]

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[6] FDA—the agency upon whose regulations EPA's regulations are "heavily" based, App.82a—has "announced that, with regard to an imprecise regulation, a study would not conclusively be deemed inadequate unless it totally failed *'even to attempt to comply.'*" *Puerto Rico Aqueduct & Sewer Auth. v. EPA*, 35 F.3d 600, 606 (1st Cir. 1994), *cert. denied*, 513 U.S. 1148 (1995)

2.a. The District of Columbia Circuit's decision in this case also conflicts with the decisions of other circuits, including the Fourth Circuit's own decision in *Weinberger*—which retains precedential force because it was affirmed in relevant part by this Court. *See id.* at 634 (affirming *Hynson* with modification to unrelated aspect of opinion). Whereas the District of Columbia Circuit held below that "'differences in the weight or credence given to particular scientific studies'" are insufficient to obtain a hearing under the FFDCA, App.13a (citation omitted), the Fourth Circuit held in *Hynson* that a hearing was required under an analogous provision of the FFDCA precisely *because* FDA and the petitioners in that case disputed the weight to be given to several "clinical studies" and "investigations." 461 F.2d at 221. Indeed, the Fourth Circuit viewed FDA's denial of a hearing in such circumstances to be so egregious as to violate due process as well as the FFDCA. *Id.* at 220-21.[7]

Likewise, the Fourth Circuit ultimately determined that a hearing was required because the material issue of whether the drug at issue was effective was subject to conflicting expert testimony. The court observed that the agency's objections to the proponent's experts

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(emphasis added). Even EPA has not accused petitioners of failing to meet that standard.

[7] As Justice Powell observed in *Weinberger*, "[t]here is also a genuine issue of procedural due process where, as in this case, the Commissioner construes his regulations to deny a hearing" where the party seeking a hearing has submitted significant evidence and expert opinions. 412 U.S. at 638 (concurring in part and concurring in the result in part). EPA's order here denying a hearing despite the ample evidence and expert data submitted by petitioners suffers from the same due process defect.

might be well-grounded, but they did not justify the denial of a hearing—"they merely create[d] a genuine question of fact to be resolved at a hearing upon proper evidence" and an examination of the experts. 461 F.2d at 221-22. In stark contrast, the District of Columbia Circuit in this case concluded that "differences in the weight or credence given to particular scientific studies" provide no basis for requiring an agency to conduct a hearing and that, quite the contrary, "a dispute between experts" over a critical issue is "fatal" to a proponents' hearing request. App.13a.

b. The District of Columbia Circuit's decision in this case also is at odds with the Ninth Circuit's decision in *Pactra Industries, Inc. v. Consumer Products Safety Commission*, 555 F.2d 677 (1977) (Kennedy, J.). In *Pactra*, the Ninth Circuit considered a separate provision of the FFDCA that incorporated the same basic "'summary-judgment type' standard" that applies to the FFDCA provision in this case, App.6a, and held that the agency must hold a hearing if it determines an objection raises a material issue of fact, *see Pactra*, 555 F.2d at 684. Under this standard, the Ninth Circuit held, a hearing may not be denied "merely because *the agency* has concluded that the scientific evidence is adequate to support its order"; instead, objections that "are neither frivolous nor inconsequential" and that concern key safety matters "raise material issues that should not be dispelled at the outset without a hearing." *Id.* (emphasis added). In this case, by contrast, the District of Columbia Circuit refused to recognize that well-supported objections raised material issues of fact and deferred entirely to the agency's own view that disputed evidence was sufficient to support its order.

c. The District of Columbia Circuit's decision likewise conflicts with the decisions of other circuits recognizing that "inherent in the very concept of administrative summary judgment" is that a "genuine and material dispute" over facts is sufficient "to qualify for an evidentiary hearing." *Puerto Rico Aqueduct & Sewer Auth. v. EPA*, 35 F.3d 600, 605 (1st Cir. 1994), *cert. denied*, 513 U.S. 1148 (1995) ("*PRASA*"). Indeed, as the First Circuit has observed, "[a]ny other assumption borders on the chimerical." *Id.*; *see also, e.g., Crestview Parke Care Ctr. v. Thompson*, 373 F.3d 743, 755 (6th Cir. 2004) ("In evaluating whether [administrative] summary judgment is proper, we do not weigh the evidence, but rather view the evidence in the light most favorable to [the hearing applicant] to divine the existence of a genuine dispute of material fact"); *J.D. ex rel. J.D. v. Pawlet Sch. Dist.*, 224 F.3d 60, 69 (2d Cir. 2000) (administrative summary-judgment procedure proper under IDEA "where the parties have had a meaningful opportunity to present evidence and the non-moving party is unable to identify any genuine issue of material fact"); *Travers v. Shalala*, 20 F.3d 993, 998 (9th Cir. 1994) (agreeing that an administrative hearing is unnecessary where there are "no disputed issues of material fact"); *E.R. Squibb & Sons, Inc. v. Weinberger*, 483 F.2d 1382, 1386 (3d Cir. 1973) (concluding that, "[b]efore this Court may affirm an action taken by summary judgment [under the FDA regulations], it must be certain that no genuine issues as to any material facts are in dispute"). As discussed, the District of Columbia Circuit's decision in this case sharply departs from that understanding.[8]

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[8] The text of the statutory hearing requirements at issue in this

3. As this Court has observed, a "principal purpose" of this Court's "certiorari jurisdiction ... is to resolve conflicts among the United States courts of appeals." *Braxton v. United States*, 500 U.S. 344, 347 (1991); *see* Sup. Ct. R. 10(a). Certiorari is also appropriate to resolve conflicts with the decisions of this Court. *See* Sup. Ct. R. 10(c). The conflicts created by the decision below and this Court's decision in *Weinberger* as well as the decisions of other circuits discussed above warrant certiorari here.

II. THE DISTRICT OF COLUMBIA CIRCUIT'S ENDORSEMENT OF EPA'S EXTRAORDINARY "CATCH-22" WAIVER RULE MERITS THIS COURT'S REVIEW

The District of Columbia Circuit compounded the damage done by its ruling on the standard for obtaining a hearing under the FFDCA by endorsing EPA's extraordinary timing rule governing what objections need be considered at all by the agency. Under this Orwellian scheme, arguments first presented *before* EPA's proposed revocation order may be deemed "recycled" (and therefore "irrelevant") when it comes to seeking a hearing on a final revocation order, while arguments first presented *after* the final revocation order in seeking a hearing may be deemed "untimely" and "waived." App.310a-13a, 23a-24a. EPA's new waiver rule thus creates a whip saw for parties seeking

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case, *Weinberger*, and the circuit cases discussed above varies in some respects. But critically, the administering agencies all (correctly) recognize that these provisions require a hearing when there are material issues of disputed fact and have promulgated nearly identical administrative summary-judgment procedures to that effect. *See* App.6a; *Weinberger*, 412 U.S. at 616, 621-22; *Pactra*, 555 F.2d at 684; *E.R. Squibb & Sons*, 483 F.2d at 1384.

a hearing and allows the agency arbitrarily to disregard timely submitted evidence and expert data establishing material issues of disputed fact as either "too early" or "too late." The District of Columbia Circuit's decision embracing that absurd rule conflicts with the decisions of this Court and other circuits, and thus underscores the need for review in this case.[9]

A. EPA's "Catch-22" Waiver Standard Violates The FFDCA And The Agency's Own Regulations

EPA's remarkable "Catch-22" waiver rule violates the text of both the FFDCA and EPA's own regulations. The FFDCA expressly provides that a party "may file objections" "*after* a regulation or order [of revocation] is issued" and never requires also raising them in comments. 21 U.S.C. § 346a(g)(2)(A) (emphasis added). By expressly allowing comments to be raised "after" EPA's final order of revocation, the FFDCA precludes agency forfeiture of arguments on the basis that they were not raised before then. *See, e.g., Jama v. Immigration & Customs Enforcement*, 543 U.S. 335, 341 (2005) ("We do not lightly assume that Congress has omitted from its adopted text requirements that it nonetheless intends to apply ....").

Likewise, EPA's own regulations permit objections to be raised "[o]n or before the 60th day *after the date of publication.*" 40 C.F.R. § 178.20(a) (emphasis added). And the agency expressly provides that "EPA

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[9] This defect provides an additional basis for granting certiorari. Even if EPA properly excluded objections under its newfound and *ultra vires* waiver rule, a hearing was still required based on the objections and evidence that EPA *did* consider, which in itself is sufficient to establish a material issue of disputed fact.

does not interpret the statute and regulations to preclude the submission of *any new* information as part of the objections phase." App.111a (emphasis added). Notwithstanding these rules, the agency repeatedly and specifically refused to consider evidence or objections responding to EPA's final revocation order. *See, e.g.*, App.210a, 233a, 262a, 267a.

Remarkably, EPA even precluded petitioners from raising objections or evidence to support a hearing request that responded to a *change* in EPA's reasoning between the proposed and final orders. For example, EPA's proposed tolerance revocation *assumed* that *100%* of crops would be treated with carbofuran. App.434a. Petitioners countered with data showing that actual usage had not exceeded *4.25%* in the past decade. App.434a-39a, 449a. In the final revocation order, EPA—for the first time—justified its 100% usage assumption on the basis that, even if exceedingly unlikely and never documented, it is "legally permissible" and thus must be considered in its risk assessment. App.235a-36a. Petitioners' objections to the proposed revocation addressed this new rationale by proposing to adopt a "cap on usage" that would make it *legally impermissible* to treat more than 2% of a watershed. App.448a, 451a-52a. The usage cap was outcome-determinative, as it would have assured that surface water exposures were within safe levels. App.448a. Yet, even though this objection was submitted in response to a new rationale in EPA's final revocation order, the District of Columbia Circuit held that EPA was free to disregard it. App.11a.

Similarly, for groundwater exposures—another outcome-determinative issue of fact disputed by petitioners—EPA advanced a new rationale for the

first time in its final revocation order: *i.e.*, that new modeling of leaching to groundwater in Wisconsin conducted in response to petitioners' comments showed that carbofuran still posed a groundwater risk. App.61a-63a. In response, petitioners' objections proposed "setbacks," which would assure a safe level of groundwater exposures notwithstanding EPA's new Wisconsin scenario. App.444a-45a, 485a-90a. Yet, the District of Columbia Circuit again upheld EPA's claim that the proposal was untimely, App.112a-18a, without even addressing the fact that the setback proposal was submitted to address grounds raised by EPA for the first time in its final order, App.362a-63a, 441a-42a.

EPA's new waiver rule—which grants the agency virtually unfettered discretion to pick and choose what objections it wishes to consider, or simply disregard, in considering hearing requests—exudes arbitrary agency action. *Cf. Ramaprakash,* 346 F.3d at 1130 ("'[T]he core concern underlying the prohibition of arbitrary or capricious agency action' is that agency 'ad hocery' is impermissible") (Roberts, J.). And the dangers of that rule are neither theoretical nor isolated. Indeed, EPA invoked this extraordinary rule less than two months after the District of Columbia Circuit's decision in this case to deny NRDC's request for a hearing under the FFDCA. *See* 75 Fed. Reg. 55,997, 56,010-11 (Sept. 15, 2010). And armed with this new rule, EPA can dismantle any hearing request.

B. In This Respect Too, The Decision Below Conflicts With The Decisions Of This Court And Other Circuits

The District of Columbia Circuit's decision upholding that novel waiver rule is at odds with the core principles underlying the decisions of this Court

and other circuits on administrative exhaustion.

As this Court held in *Sims v. Apfel*, 530 U.S. 103, 107 (2000), "requirements of administrative issue exhaustion are largely creatures of statute." But as explained, the statute at issue—the FFDCA—imposes no exhaustion requirement. Nor do any of the agency's own regulations. To the contrary, EPA's regulations explicitly provide that parties may raise arguments "after" the comment stage. *Supra* at 27; *see Sims*, 530 U.S. at 113 (O'Connor, J., concurring in part and concurring in the judgment) ("Requiring issue exhaustion is particularly inappropriate here, where the regulations and procedures of the [agency] affirmatively suggest that specific issues need not be raised before the Appeals Council."). Neither EPA nor the District of Columbia Circuit was free retroactively to impose new issue exhaustion requirements in this case where governing "regulations do not require [such] issue exhaustion." *Sims*, 530 U.S. at 108.[10]

The decision below also conflicts with the decisions of other circuits. The Ninth Circuit, for example, has held that it is sufficient to defeat a claim of waiver that an agency merely "understood plaintiffs to raise the issue of whether [it] complied with [the relevant statute]." *Native Ecosystems Council v. Dombeck*, 304 F.3d 886, 899 (9th Cir. 2002); *see also id.* (A party need only "afford [the agency] the opportunity to rectify the

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[10] While this Court has, on occasion, permitted "issue-exhaustion requirement[s]," they have largely followed from "analogy to the rule that appellate courts will not consider arguments not raised before trial courts." *Sims*, 530 U.S. at 108-09; *see also Dep't of Transp. v. Public Citizen*, 541 U.S. 752, 764 (2004). Here, there can be no doubt that petitioners had raised all relevant arguments before EPA, and that EPA was alerted to them.

violations ... alleged."); *Forest Guardians v. United States Forest Serv.*, 495 F.3d 1162, 1170-73 (10th Cir. 2007) (citing *Dombeck* with approval). And even if that minimal requirement is not met, the Ninth Circuit has held that it will consider arguments *never* raised before an agency as long as the agency had "independent knowledge of the issues that concerned [petitioners]." *'Ilio'Ulaokalani Coal. v. Rumsfeld*, 464 F.3d 1083, 1092-93 (9th Cir. 2006). The Third Circuit similarly requires only that an agency "was on notice of, and had an opportunity to consider and decide, the same claims now raised in federal court." *Kleissler v. United States Forest Serv.*, 183 F.3d 196, 202 (3d Cir. 1999).

EPA has never denied that it had both notice and an opportunity to consider petitioners' objections, including their label amendments. EPA simply refused to do so. In at least the Third and Ninth Circuits, EPA's arbitrary waiver rule would not be enforced. But in stark contrast, the District of Columbia Circuit blessed EPA's rule requiring that petitioners raise all arguments twice, at both stages of proceedings—although petitioners will still run headlong into EPA's other waiver whip-saw, by purportedly "recycling" the argument/data at the second stage. That conflict of authority also warrants this Court's review.

III. THE QUESTION PRESENTED HAS FAR-REACHING SIGNIFICANCE AND IS UNDENIABLY IMPORTANT

This case concerns a matter of exceptional national importance. For more than four decades, EPA has thwarted Congress's express hearing requirement under the FFDCA—implausibly failing to identify a single disputed material fact that it believed justified a hearing. It is safe to say that EPA has never seen a

hearing request it likes—and never will. EPA's obstinac in refusing to give effect to the FFDCA's hearing requirement and its own summary-judgment procedures is if anything even more institutionalized and evident than was FDA's before this Court granted certiorari in *Weinberger*, and thus is even more worthy of review and repudiation by this Court.

Nor is the damage limited to EPA and pesticides. The FFDCA hearing requirement and administrative summary-judgment procedures at issue in this case are comparable to other hearing requirements administered by EPA, FDA, and CPSC concerning an array of important products and goods: from medical devices, prescription drugs, agriculture, food and food additives and cosmetics, to a myriad of consumer goods. Given that such products account for a substantial portion of the national economy, Congress understandably desired greater procedural protections for regulatory decisions concerning the availability of such products. Moreover, these protections are particularly important where, as here, an agency seeks to ban a product that regulated parties like petitioners have been selling or using safely for many years.

The District of Columbia Circuit's willingness to accept uncritically EPA's unrealistic assumptions underscores the need for review by this Court. EPA's assumption of 100% carbofuran usage, for example, is not supported by *any* record evidence and instead is squarely contradicted by petitioners' evidence that actual usage did not exceed 4.25% in *any* relevant area. *Supra* at 9. But by adopting such fantastic assumptions, EPA—with the blessing of the District of Columbia Circuit—may ban virtually any product it dislikes, threatening *all* of the protections of the

FFDCA. After all, under such unrealistic modeling, everything from caffeine to water is potential deadly. And if EPA's 100% carbofuran usage assumption in this case is sufficient to withstand a hearing request, then EPA also presumably could regulate automobile emissions under a model where all cars will be driven hundreds of miles a day, for example—which is also perfectly legal and yet just as unrealistic as the assumption on which the hearing was denied here.

The fact that this case was decided by the District of Columbia Circuit heightens the importance of the ruling under review. The District of Columbia Circuit—with its nearly ubiquitous jurisdiction over administrative agencies—unquestionably exerts enormous influence on the field of administrative law. *See* John G. Roberts, Jr., *What Makes the D.C. Circuit Different? A Historical View*, 92 Va. L. Rev. 375, 389 (2006) ("Whatever combination of letters you can put together [in an agency's name], it is likely that jurisdiction to review that agency's decision is vested in the D.C. Circuit."); Richard J. Pierce, Jr., *The Special Contributions of the D.C. Circuit to Administrative Law*, 90 Geo. L.J. 779, 779 (2002) ("[T]he D.C. Circuit has long dominated and played a major role in shaping" administrative law).

This Court itself has recognized the heightened impact that decisions of the District of Columbia Circuit have on agency action. As the Court has observed, because "the vast majority of challenges to administrative agency action are brought to the ... District of Columbia Circuit ... the decision of that court ... will serve as precedent for many more proceedings for judicial review of agency actions than would the decision of another Court of Appeals."

Vermont Yankee Nuclear Power Corp. v. NRDC, 435 U.S. 519, 535 n.14 (1978); *see also* John M. Golden, *The Federal Circuit and the D.C. Circuit: Comparative Trials of Two Semi-Specialized Courts*, 78 Geo. Wash. L. Rev. 553, 562 (2010) (noting that this Court has historically "prioritized review of the D.C. Circuit's administrative law"). That holds true for review of agency orders denying evidentiary hearings as well.

In *Weinberger*, the Solicitor General advised this Court that the question presented in that case—which concerned when an evidentiary hearing is required under an analogous provision of the FFDCA and administrative summary-judgment procedures governing FDA's licensing of new drugs—was of "great importance" to FDA, the "drug industry," and "American consumer." Pet. for Cert. 20, *Weinberger*, 412 U.S. 609 (1973) (No. 72-394). The same goes for the agency, industries, and Americans affected by the hearing requirement at issue in this case concerning the safety of pesticides, not to mention the agencies, industries, and Americans affected by the many analogous hearing provisions discussed above.

Of course, here, from the government's perspective, the shoe is on the other foot compared to *Weinberger* (where the government sought review of a decision holding that a hearing was *required* under the same type of administrative summary-judgment procedures at issue here). But the question presented is no less important when it comes to ensuring that the public's right to a hearing is respected. Indeed, the Court's intervention is if anything even more warranted here.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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FEBRUARY 16, 2011

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